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No. 98-1768

IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,
v.
PLAINTIFF'S LEGAL COMMITTEE,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

MOTION FOR LEAVE TO FILE AND BRIEF FOR *AMICUS CURIAE* MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

Pursuant to Supreme Court Rule 37.2, the Medical Device Manufacturers Association ("MDMA") moves the Court for leave to file the attached *amicus curiae* brief in support of petitioner, The Buckman Company.[1] This case addresses the scope of product liability exposure in the medical device industry. As a national trade association representing nearly 130 independent manufacturers of medical devices, diagnostic products and health care information systems, MDMA is well-qualified to inform the Court of the great significance of this case for the medical device industry and the consuming public.

As MDMA's accompanying brief explains, direct conflicts in the lower courts over the scope of preemption have created a confusing pattern of tort liability exposure from state to state that threatens to disrupt nationwide availability of medical devices. In addition, the Third Circuit's holding that fraud on the agency claims escape preemption would undermine the public health by deterring beneficial "off-label" uses of medical devices and create delays in the Food and Drug Administration's premarket clearance of critical new devices. Furthermore, such fraud claims would allow private parties to seek remedies under state law that would interfere with the Food and Drug Administration's unique responsibility to investigate and punish fraud in its premarket clearance processes.

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[1] Counsel for petitioner consented to the filing of MDMA's brief, but counsel for respondent declined.

MDMA respectfully submits that it has the perspective to inform the Court about the significance of these issues that arise from this case, and that MDMA's brief would aid the Court in its decision regarding The Buckman Company's petition for certiorari. Accordingly, MDMA requests the Court to grant its motion to file the attached *amicus curiae* brief.

Respectfully submitted,

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BRIEF FOR *AMICUS CURIAE* MEDICAL DEVICE MANUFACTURERS ASSOCIATION IN SUPPORT OF PETITIONER

INTEREST OF *AMICUS CURIAE*

The Medical Device Manufacturers Association ("MDMA") is a national trade association based in Washington, D.C. that represents nearly 130 independent manufacturers of medical devices, diagnostic products and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products. To achieve these goals, MDMA represents its members' collective interests before the United States Congress, the Food and Drug Administration ("FDA"), other federal agencies, and courts that develop, implement or interpret policies that affect the medical device industry. MDMA has a significant interest in this case because it raises important product liability issues with broad implications for the entire medical device industry and the public health.[1]

SUMMARY OF ARGUMENT

The Court should grant the petition because it presents issues of critical importance to the public health, and because conflicting lower court decisions have created confusion and

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[1] No counsel for any party authored this brief in whole or in part, and no person or entity other than *amicus curiae* and its members made a monetary contribution to the preparation or submission of the brief.

uncertainty regarding the scope of tort liability in the medical device industry.

1. The Third Circuit held that the express preemption provision of the Medical Device Amendments of 1976 does not preempt state common law claims alleging fraud on the FDA. This case presents important public health questions, because if such claims are not barred by preemption, they will undermine the FDA's capacity to make critical new medical devices available promptly for patient treatment. Because most new medical devices cannot be marketed without prior FDA clearance, delays in the clearance process postpone availability of important therapies. Fraud on the agency claims such as those preserved by the Third Circuit would threaten delays in the FDA's premarket clearance process — and create associated delays in device availability — for two major reasons.

First, such claims would entangle agency personnel in tort litigation between private parties. The claims at issue in this case are premised upon the assertion that FDA product clearance was obtained through fraud. The FDA officials who granted clearance would be critical witnesses to the alleged fraud, because their personal knowledge primarily would determine whether a misrepresentation occurred, and if so, whether it affected premarket clearance of a medical device. Entangling FDA officials in tort litigation as witnesses would divert them from their important product clearance functions, thereby delaying the availability of critical medical devices.

Second, fraud on the agency claims would create incentives to burden the FDA with additional and unnecessary submissions of information. If fraud on the agency claims are preserved from preemption, as the Third Circuit held, manufacturers will attempt to protect themselves against fraud liability by submitting to the agency all information that is even arguably relevant to product

clearance, to guard against later allegations that there were material omissions in communications with the agency. The resulting burden on the agency to review the information submitted would further delay product clearances, with a corresponding detrimental effect on the public health.

2. This case also presents important public health questions because fraud on the agency claims would deter "off-label" use of medical devices. The FDA and the medical profession have long recognized that when the agency clears a product for one use, it may well have important unapproved uses as well. Cutting-edge therapies are frequently developed through off-label uses of devices cleared by the FDA for a different use. Fraud claims of the type at issue in this case — which allege that the manufacturer illegally promoted off-label uses — would deter companies from seeking FDA clearance for such uses. In addition, such fraud claims would deter dissemination of off-label use information to health care practitioners, even through dissemination is permissible under federal law.

3. Direct conflicts in the lower courts have created great uncertainty whether the MDA preempt *any* tort claims, and if so, whether fraud on the agency claims are preempted. As a result, a confusing pattern of liability exposure exists from state to state. The conflicts threaten to undermine nationwide availability of critical medical devices, because device manufacturers currently have a strong incentive to pick and choose the states where they will and will not sell their products. Only this Court can resolve the conflicts by granting the petition.

4. Fraud claims of the type preserved by the Third Circuit interfere with the FDA's unique responsibility to investigate and punish fraud in its premarket clearance processes. The FDA has extensive authority to remedy such fraud, and the proper role of a private party is to refer alleged frauds for investigation by the agency, not to pursue

independent remedies for fraud under state law. The Court should grant the petition to maintain the FDA's authority to remedy fraud on the agency.

ARGUMENT

I. This Case Presents Important Public Health Questions Because Claims for Fraud on the Agency Would Undermine the FDA's Capacity to Make Critical New Medical Devices Available Promptly for Patient Treatment

The Third Circuit held that the express preemption provision of the Medical Device Amendments of 1976 ("MDA") does not preempt state common law claims alleging fraud on the FDA. This case presents important public health questions, because if such claims are not barred by preemption, they will undermine the FDA's capacity to make critical new medical devices available promptly for patient treatment. Federal law prohibits manufacturers from distributing most new medical devices without prior clearance from the FDA (*see, e.g.*, 21 U.S.C. §§ 360e, 360(k) (1994 & Supp. 1999)), and as a result, delays in premarket clearance profoundly affect patients' health by postponing their access to innovative device therapies. The FDA has recognized the importance of streamlining its premarket clearance processes to "bring needed therapies to patients as quickly as possible." *Hearing Before the Subcomm. On Oversight & Investigations of the House Comm. On Commerce* (Sept. 23, 1997) (statement of Michael A. Friedman, Lead Deputy Commissioner, FDA). Yet fraud on the agency claims, such as those preserved from preemption by the Third Circuit, would hamper the FDA's ability to provide prompt premarket clearance for devices that could substantially improve the health of patients.

A. Fraud on the Agency Claims Would Delay Premarket Clearance by Entangling FDA Personnel in Litigation Between Private Parties

Until the Third Circuit's decision in this case, most lower courts had held (both before and after *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)) that the MDA preempt claims for fraud on the FDA. *See* Pet. at 11-15. If such claims are instead preserved from preemption, as the Third Circuit held, they will increasingly cause delays in premarket clearance by entangling FDA personnel in litigation between private parties. Fraud claims such as those at issue here assert that misrepresentations were made to FDA officials responsible for premarket clearance decisions, who in turn authorized marketing of a medical device in reliance on the misrepresentations. These officials obviously would be critical witnesses to the alleged fraud in a tort suit, because their personal knowledge primarily would determine whether a misrepresentation occurred, and if so, whether it affected premarket clearance of a medical device.

Given their unique knowledge of the facts at issue in a fraud on the agency claim, FDA officials would be important witnesses for both the plaintiff and defendant. Indeed, in the present case, plaintiffs claim that defendants misled agency officials, yet defendants contend that their course of action (now alleged to be fraudulent) was *suggested* by the FDA. *See* Pet. at 17 n.8. For both parties, the witnesses who could provide the best evidence to resolve factual disputes like this one would be the FDA officials who reviewed and acted on the manufacturer's premarket clearance submissions.

Because they would be such important witnesses in fraud on the agency claims, FDA officials would be vulnerable to entanglement in tort litigation. Although the FDA, like other agencies, has promulgated "housekeeping" regulations that purport to restrict its obligation to respond to third party subpoenas issued in litigation between private parties, *see* 21

C.F.R. § 20.1, those regulations do not guarantee the agency any protection against involvement in tort suits. The regulations themselves authorize testimony if the public interest so requires. *See id.; In re U.S. Bioscience Sec. Litig.*, 150 F.R.D. 80 (E.D. Pa. 1993) (enforcing subpoenas for deposition testimony of FDA employees in private securities litigation).

Furthermore, at least since the Ninth Circuit's decision in *Exxon Shipping Co. v. Department of Interior*, 34 F.3d 774 (9th Cir. 1994), the lower courts increasingly have cast substantial doubt on the validity of such housekeeping regulations. In *Exxon*, the Ninth Circuit held that five federal agency heads could not rely on their agencies' housekeeping regulations to prevent subordinate employees from testifying pursuant to third party deposition subpoenas. The Ninth Circuit rejected the argument that this Court's decision in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951) permitted federal agencies to refuse to allow their employees to respond to valid third-party subpoenas by invoking such regulations. *Exxon*, 34 F.3d at 778.[2] The court concluded

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[2] In *Touhy*, the Court held that an FBI official could not be held in contempt for obeying an order by his superior — the Attorney General — to refuse production of documents pursuant to a third-party subpoena. *Touhy* therefore addressed the question whether the Attorney General, as head of an agency, had authority to "centraliz[e] determination as to whether subpoenas *duces tecum* will be willingly obeyed or challenged" by implementing housekeeping regulations that "withdraw from his subordinates the power to release department papers." 340 U.S. at 467-68. The Court expressly refused to reach the question whether the agency

(Footnote cont'd on next page)

that just like any other witness, a federal employee witness is required to comply with a federal court subpoena under the standards set forth in Fed. R. Civ. P. 45. *Id.* at 779. Following *Exxon*, numerous other lower courts also have held that government agencies — including the FDA — may not rely on housekeeping regulations to withhold information sought through third-party subpoenas. *See, e.g., Houston Business Journal, Inc. v. Office of Comptroller of Currency*, 86 F.3d 1208, 1212 (D.C. Cir. 1996) (housekeeping regulations do not authorize withholding subpoenaed documents in conflict with Fed. R. Civ. P. 45); *Connaught Labs., Inc. v. SmithKline Beecham*, 7 F. Supp. 2d 477 (D. Del. 1998) (rejecting restrictions of FDA housekeeping regulations and enforcing subpoenas for testimony of FDA employees in patent litigation between private parties).

Once subpoenas were issued in a fraud case, the drain on the time and resources of agency personnel required for subpoena responses would be substantial. The scope of relevant testimony and documents potentially would be quite broad, because every communication between the manufacturer and the FDA regarding premarket clearance could be a source of evidence in a case alleging fraud on the agency, and such communications are numerous; the FDA's review of premarket clearance submissions is a collaborative process between the manufacturer and the agency, involving frequent dialog over a period of months or even years.

(Footnote cont'd from previous page.)

itself had a "privilege against disclosure" (*id.* at 468, 469 & n.9) allowing it to "refuse to produce government papers." *Id.* at 469.

For example, the agency has long encouraged early meetings between manufacturers and FDA officials to exchange information about a new device even before the FDA has approved clinical studies that may be required for eventual premarket clearance. *See Guidance on IDE Policies and Procedures* at 1 (Jan. 20, 1998) <http://www.fda.gov/cdrh>; *Goals and Initiatives for the IDE Programs* IDE Mem. #D95-1, at 2 (July 12, 1995) <http://www.fda.gov/cdrh/d951.htm1>. In 1997, Congress endorsed a similar interactive process by amending the Food, Drug, and Cosmetic Act to require the FDA, upon written request, to meet with the applicant for a premarket approval application ("PMA") within 100 days after the PMA is filed. 21 U.S.C. § 360e(d)(3). The agency does not limit itself to this required meeting and goes "beyond the [statutory] requirements by encouraging 'exploratory' meetings very early in the premarket review process and continued interactions throughout the review process." *FY 2000 Budget Request* at 1 <http://www.fda.gov/oc/oms/ofm/budget/devnctrtab.htm>. The FDA has agreed "to communicate with each firm at least every four weeks subsequent to the 100-day meeting." *FDA/CDRH Annual Report FY 1998* at 1 <http://www.fda.gov/cdrh/index.html>.

A fraud on the agency claim potentially would require FDA personnel to respond to discovery concerning each of these communications, thereby diverting substantial resources from review of premarket clearance applications. Distracting agency officials from their critical device review functions would undermine prompt clearance of promising new therapies that could substantially improve the public health.

B. Fraud on the Agency Claims Would Delay Premarket Clearance by Creating Incentives to Burden the FDA With Needless Submissions of Information

If fraud on the agency claims are preserved from preemption, as the Third Circuit held, they also will delay premarket clearance by creating incentives to burden the FDA with additional submissions of information. Manufacturers would attempt to protect themselves against fraud liability by submitting to the agency all information that is even arguably relevant to product clearance, to guard against later allegations that there were material omissions in communications with the agency. *See* Pet. at 18.

These additional information submissions would be unnecessary. For example, in the present case, the agency had no need for additional information to determine whether it had been defrauded. Only three months passed between the premarket clearance application that plaintiffs allege revealed defendants' true intended use (spinal surgery) and the application that plaintiffs allege fraudulently misrepresented the intended use as for the long bones in the arms and legs. Pet. App. at 5a. The FDA officials responsible for reviewing these applications manifestly had full notice that the intended use had been changed — and according to the petition had in fact *encouraged* the change (Pet. at 17 n.8) — at a time when it was well known at the agency that "[i]n practice, surgeons often use orthopedic screws which FDA has cleared for other purposes" in spinal surgery instead. *See* James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71, 77 (1993) (citing FDA, Update on Pedicle Screws).

Though needless, the additional information submissions would have a deleterious effect on the FDA's product clearance work. Once the information was submitted, it

would need to be reviewed by FDA personnel who already have limited budgetary resources. Furthermore, in recent years, the number of FDA employees in the Office of Device Evaluation ("ODE") — the office responsible for reviewing premarket clearance applications — has steadily fallen. 1996 ODE Annual Report at 1; 1997 ODE Annual Report at 1; 1998 ODE Annual Report at 2, *supra*. Increasing the amount of information for these officials to review would increase product clearance times and delay the marketing of innovative therapies for patient use.

The tort system would create this effect after FDA, both on its own initiative and with Congressional urging, has made great strides to reduce clearance times by *diminishing* the information required to be submitted for agency review. *See, e.g.*, 21 U.S.C. § 360c(a)(3)(C) (requiring the FDA to consider "whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls"). For example, the FDA now requires submission of less information for 510(k) applications regarding low risk devices (because clearance decisions are based primarily on descriptive information and a labeling review) than it does for high risk devices (for which clearance decisions rely on performance data). *The New 510(k) Paradigm* at 3 (Mar. 20, 1998) <http://www.fda.gov/cdrh/ode/parad510.html>. The agency also requires more information in a 510(k) application seeking initial clearance for a device than it does for an application seeking clearance for a change in a previously marketed device. *FY 2000 Budget Request* at 2, *supra*. To reduce submission requirements regarding 510(k) applications further, the FDA also permits manufacturers to certify compliance with certain material and performance standards in lieu of submitting information demonstrating compliance. *Id.* Because it has streamlined the submission process, FDA review time for 510(k) applications during

fiscal year 1998 was only *half* what it was only four years earlier. *FDA/CDRH Annual Report FY 1998* at 7, supra.

Fraud claims of the type preserved by the Third Circuit would undermine this important progress, with a corresponding detriment to the public health. In so doing, such claims would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)) — a circumstance that this Court has long viewed as giving rise to implied preemption of state law. This case therefore presents the Court with an excellent opportunity to address the federal-state balance in an area that directly affects the public health.

II. This Case Presents Important Public Health Questions Because Claims for Fraud on the Agency Would Undermine Valuable Off-Label Uses of Medical Devices

This case also presents important public health questions because fraud claims of the type at issue in this case would undermine "off-label" uses of medical devices. Judge Cowan's dissent below explained that "[t]he FDA and the medical community have long recognized the importance of doctors' off-label uses of medical products (uses not indicated on the label or approved by the FDA)." Pet. App. at 28a. Cutting-edge therapies are frequently developed through off-label uses of devices cleared by the FDA for a different use (*see, e.g., id.* at n.1), in part because medical science innovation moves at a faster pace than the agency's review process. As the discussion below explains, fraud claims of the type preserved by the Third Circuit would create incentives that undermine off-label uses and their related benefits to the public health.

A. Fraud on the Agency Claims Would Undermine Innovation by Discouraging Manufacturers From Seeking Premarket Clearance for Off-Label Uses

When it enacted the MDA, Congress intended to protect innovations in device technology from being "stifled by unnecessary restrictions" (H.R. Rep. No. 94-853 at 12 (1976)), thereby stimulating research and development of "sophisticated, critically important medical devices." S. Rep. No. 94-33 at 2 (1976). Yet as Judge Cowan properly noted in his dissent, the Third Circuit majority's preservation of fraud on the agency claims from preemption is "likely to hinder technological growth" (Pet. App. 27a) by discouraging manufacturers from seeking FDA premarket clearance for off-label uses.

Because many medical devices have multiple uses, it is not uncommon for a manufacturer to obtain premarket clearance for one use and later seek clearance for a different use. For example, a pain control device may be cleared by the FDA to treat pain of one particular cause and subsequently cleared for use to relieve pain of other causes, just as in the present case, the same orthopedic device was the subject of premarket clearance applications for use in two different skeletal structures. The FDA finds multiple applications for different uses of the same device unremarkable and considers each application independently on its merits. *See, e.g.*, 21 U.S.C. § 360c(i)(1)(E) (generally restricting agency review of intended use to consideration of the labeling submitted with 510(k) application). As Judge Cowan explained, expanding the uses for medical devices in this manner "will often be a very desirable source of progress and innovation in medical products." Pet. App. at 26a. It therefore is not surprising that when Congress amended the Food, Drug, and Cosmetic Act in 1997, it emphasized that it wanted "to encourage that these new uses be included on the product label." H.R. Conf. Rep. No. 105-399 at 99 (1997).

If fraud on the agency claims such as those at issue in this case were preserved from preemption, they would discourage manufacturers from seeking clearance for new uses. In the present case, the fraud claim rests on the premise that if the manufacturer has filed separate applications seeking clearance for two different uses of the same device, one must represent the true intended use, and the other must be fraudulent. Preserving such claims from preemption would make manufacturers concerned that in seeking clearance for new uses, they would render themselves vulnerable to tort claims for fraud relating to the clearance they received for the original use. The manufacturers would, in the words of Judge Cowan, consider themselves precluded, "via the penalty of fraud liability, from seeking approval for another use." Pet. App. at 26a. Because preserving such fraud claims from preemption would undermine the important public health benefits that derive from innovative new uses of medical devices, this case presents important issues worthy of Supreme Court review.

B. Fraud on the Agency Claims Would Chill Dissemination of Information Regarding Off-Label Use

Fraud on the agency claims of the type at issue in this case also would chill manufacturers' dissemination of information to health care practitioners regarding off-label uses, thereby undermining those uses and their associated benefits. If a manufacturer were deterred from seeking FDA clearance for the off-label use for the reasons described above, federal law would prohibit the manufacturer from affirmatively initiating dissemination of information regarding that use. Federal law permits manufacturers to initiate distribution of such information only if they submit an application seeking clearance for the off-label use, certify that they will submit such an application in the future, or

obtain an exemption from the agency. 21 U.S.C. § 360aaa-3(a).

Furthermore, fraud on the agency claims would deter manufacturers from disseminating off-label use information even if they did apply for an appropriate clearance. Judge Cowan was rightly concerned that following the Third Circuit's decision, a manufacturer might be exposed to fraud liability for "secur[ing] approval for one use" and "distribut[ing] materials on off-label uses in compliance with the statute . . . while its primary purpose is to obtain approval for the off-label uses." Pet. App. at 30a n.3. Judge Cowan properly perceived that in the hands of plaintiffs' counsel, off-label use information distributed by a manufacturer would be cast as evidence of alleged fraud on the agency, even if its dissemination was in full compliance with federal law. This exposure would further chill distribution of information regarding innovative therapies that benefit the public health.

III. The Court Should Grant the Petition to Maintain Nationwide Availability of Medical Devices by Establishing Uniformity in an Important Area of the Law Rife With Uncertainty and Conflict

When it enacted the MDA, Congress concentrated regulation of medical devices at the federal level, believing that it could minimize uncertainty, promote uniformity, and spur innovation that would not be "stifled by unnecessary restrictions." H.R. Rep. No. 94-853 at 12. One means of achieving this goal of uniformity was the MDA express preemption provision, which Congress intended to be a "general prohibition on non-Federal regulation." *Id.* at 45. In the wake of *Medtronic*, however, differing lower court opinions have undermined this intended uniformity, leaving the scope of the preemption provision — and the scope of tort liability for medical device manufacturers — plagued by uncertainty. The Court should grant the petition to clarify the

contours of the preemption provision and promote the uniformity intended by Congress.

The MDA express preemption provision invalidates certain state law requirements "establish[ed] or continue[d] in effect with respect to a device intended for human use." 21 U.S.C. § 360k. The Third Circuit held that fraud claims concerning the bone screw at issue in this case were not preempted because (*inter alia*) they did not establish "a state 'requirement' 'with respect to' that device." Pet. App. 13a. In so holding, the Court of Appeals appears to have joined the Tenth Circuit in concluding that tort claims in general are exempt from express preemption under section 360k. *See Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997).

On this issue, the Third and Tenth Circuits are in direct conflict with the Fourth, Sixth, Seventh and Ninth Circuits, which hold that section 360k does encompass tort claims. *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 912 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998); *Papike v. Tambrands, Inc.*, 107 F.3d 737, 741 (9th Cir.), *cert. denied*, 118 S. Ct. 166 (1997); *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1097-98 (6th Cir. 1997), *cert. denied*, 118 S. Ct. 850 (1998); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996). The petition makes clear that this conflict is magnified because in eight states within these Circuits, the applicability of preemption to tort claims differs depending upon whether a case is brought in state or federal court. *See* Pet. at 23-24 & n.14 (citing cases).

Furthermore, as the Third Circuit recognized, its opinion also established a direct conflict with the Seventh Circuit on the specific question whether fraud on the agency claims are preempted. *See* Pet. App. at 17a n.5 (citing *Mitchell*, 126 F.3d 902). And even within the Third Circuit, the scope of liability remains confused. The petition properly notes that the state law fraud claims preserved by the Third Circuit would impose a subjective test for determining the intended

use of a device, whereas federal law imposes a conflicting objective test. *See* Pet. at 27.

The obvious effect of the conflicts described above is that manufacturers currently face a pattern of differing tort liability exposure from state to state. For example, in the states of the Third Circuit, where manufacturers now may be sued (in federal court) for fraud on the agency as a result of the lower court's opinion, the scope of potential liability is extraordinarily broad. According to the Third Circuit, a plaintiff may prevail on such a claim simply by proving that a product clearance was obtained through fraud, and that the product caused injury. Pet. App. at 9a (citing elements of fraud cause of action), 18a (citing cases). The implication of the Third Circuit's analysis is that a manufacturer could be held liable for *any* injury caused by its product, even if it was not defective, and even if it was manufactured, designed and distributed with reasonable care and adequate warnings.

Given the vast differences in liability exposure in different jurisdictions, manufacturers of critical medical devices currently have a strong incentive to pick and choose the states where they will and will not sell their products. The conflicts therefore threaten to undermine the nationwide distribution of medical devices, leaving patients in some states without therapies that would prolong and enhance their lives. Nothing could be further from the result that Congress intended from a unified federal regulatory system with state interference proscribed by the preemption provision's "general prohibition on non-Federal regulation." H.R. Rep. No. 94-853 at 45.

As the petition notes, *see* Pet. at 20, the conflict on the question whether *any* tort claims are preempted derives from ambiguities in *Medtronic, Inc. v. Lohr*, and particularly from the opinions signed by Justice Breyer, who joined the Court's opinion (which casts doubt on MDA preemption of tort claims) but also authored a separate opinion emphasizing that

such preemption would not be "rare." 518 U.S. at 508. And the conflict on the specific question whether fraud on the agency claims are preempted stems at least in part from the fact that *Medtronic* did not address such a claim at all. *See* Pet. at 14. The lower courts cannot resolve these conflicts on their own. Only this Court can clarify the law in this important area and re-establish certainty and uniformity regarding product liability exposure for medical devices.

IV. The Court Should Grant the Petition to Prevent Interference with the FDA's Authority to Remedy Fraud in its Premarket Clearance Processes

The discussion above explains that Congress intended the MDA to establish a unified federal regulatory structure immune from state interference. State common law fraud claims such as those preserved by the Third Circuit would allow tort plaintiffs to interfere with the FDA's unique authority to police fraud in its own processes. In the present case, for example, the plaintiffs allege that the agency was defrauded, even though the agency — with all relevant facts before it — does not appear to agree. The Court also should grant the petition to prevent such intermeddling with the FDA's unique responsibility to remedy fraud in its premarket clearance processes.

Under federal law, the agency has extensive tools at its disposal to root out and punish fraud in its premarket clearance processes. The agency proceeds under its "fraud policy" to investigate "acts such as submitting fraudulent applications, making untrue statements of material facts, or giving or promising bribes or illegal gratuities [that] may call into question the integrity of some or all of the applicant's submissions to the agency." 56 Fed. Reg. 46,191, 46,199 (1991). If fraud is uncovered, the FDA exercises its authority "under applicable statutes and regulations, to refuse to approve the application (in the case of a pending application) or to proceed to withdraw approval (in the case of an

approved application)." *Id.* at 46,200. The FDA also refers fraud cases for criminal prosecution by the Department of Justice, because violation of the FDCA's prohibitions with "intent to defraud or mislead" is a felony. 21 U.S.C. §§ 331, 333(a)(2); *see also United States v. Cambra*, 933 F.2d 752, 755 (9th Cir. 1991) (FDCA felony provision prohibits fraud on government enforcement agencies). The federal Sentencing Guidelines include a sentencing enhancement for FDCA felony violations involving fraud if the government obtains a conviction. U.S.S.G. §§ 2N2.1(b)(1); 2F1.1.

In this regulatory scheme, with its "general prohibition on non-Federal regulation" (H.R. Rep. No. 94-853 at 45), the proper role of a private party is to *refer* alleged frauds to the agency for investigation, not to act as a private attorney general pursuing independent remedies under state law. For example, the FDA's "Citizens Petition" process allows any person to request the agency to withdraw a product clearance obtained through fraud. *See* 21 C.F.R. § 10.30. Respondent is well aware of this process, having filed a Citizens Petition (with 1,000 pages of supporting material) alleging fraud on the agency and seeking withdrawal of one manufacturer's bone screw product clearance. Citizens Petition, FDA Docket No. 98P-0623 (July 24, 1998). In addition, private parties may bring alleged frauds to the attention of the agency through contacts with FDA enforcement personnel. The Court should grant the petition for certiorari to keep responsibility for remedying fraud on the agency where it properly belongs — in the hands of the FDA.

CONCLUSION

For the reasons set forth above, the court should grant the petition for certiorari.

Respectfully submitted,

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